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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

FRESENIUS KABI USA, LLC,	:	
	:	
Plaintiff,	:	Case No: 16-cv-04544
v.	:	(SDW)(LDW)
	:	
PAR STERILE PRODUCTS, LLC and PAR PHARMACEUTICAL COMPANIES, INC.,	:	**ORAL ARGUMENT REQUESTED**
	:	
Defendants.	:	
	:	

PLAINTIFF FRESENIUS KABI USA, LLC'S SUPPLEMENTAL BRIEF ON SUMMARY JUDGMENT DISPOSITION

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

GLOSSARY

ANDA	Abbreviated New Drug Application
API	Active pharmaceutical ingredient
Bachem	Bachem Americas, Inc.
BCN	BCN Peptides
CA3 Op.	Opinion, *Fresenius Kabi USA, LLC v. Par Sterile Prods., LLC*, No. 20-1618 (3d Cir. Feb. 11, 2021)
DMF	Drug Master File
Fresenius Kabi	Fresenius Kabi USA, LLC
LOA	Letter of Authorization
Orange Book	*Approved Drug Products With Therapeutic Equivalence Evaluations*, an FDA publication that lists FDA-approved drug products and any related patents
Par	Par Sterile Products, LLC and Par Pharmaceutical Companies, Inc., collectively
Par's Patents	The following patents listed in the *Orange Book* for Vasostrict: U.S. Patent Nos. 9,375,478, 9,687,526, 9,744,209, 9,744,239 and 9,750,785. (Dkt. Nos. 187-19; 187-20; 187-21; 187-22; 187-23)
PolyPeptide	PolyPeptide Laboratories Sweden AB
Vasostrict	Par's FDA-approved vasopressin injection product

INTRODUCTION

Binding Third Circuit precedent holds that when a monopolist uses exclusive dealing contracts "to prevent one or more new or potential competitors from gaining a foothold in the market … its success in that goal is not only injurious to the potential competitor but also to competition in general." *LePage's Inc. v. 3M*, 324 F.3d 141, 159-62 (3d Cir. 2003) (en banc) (upholding jury verdict that defendant violated the antitrust laws by using cash incentives to achieve exclusive deals in order to eliminate a lower-priced competitor). Thus, Fresenius Kabi's claims—premised upon Par successfully delaying lower-priced generic competition for a life-saving drug **Topics C, F** —must be heard by a jury.[1] Every day Par's conduct continues is another day Par lines its own pockets at the expense of consumers and patients. It is no wonder Third Circuit Judge Joseph Greenaway called this an "important" case.[2]

Par did not achieve its present-day monopoly on the merits. Instead, after becoming the sole FDA-approved vasopressin injection manufacturer, Par blocked and delayed generic competition **Topics C, F**

[1] *See also In re Glumetza Antitrust Litig.*, No. 19-C-05822, 2021 WL 1817092, at *6 (N.D. Cal. May 6, 2021) ("*Glumetza*") (denying summary judgment because "[a] reasonable trier of fact could … conclude that defendants' restraint of the market delayed generic entry, stifled competition, and caused [consumers] to pay more[.]").
[2] *See* Oral Argument Recording at 1:19:43–44, available at https://www2.ca3.uscourts.gov/oralargument/audio/20-1618_FreseniusKabiv.ParSterileProducts.mp3.

Topics C, F [3] Indeed, Par's President publicly bragged to investors that securing API on an "exclusive basis" was its "defense" to competition.[4] Par then secured what Fresenius Kabi's evidence shows are invalid patents for a drug that has existed over 100 years.

Par's conduct targeted Fresenius Kabi, which had been Par's sole competitor for grandfathered vasopressin.[5] Topics C, F [6] Topics C, F [7] Topic I [8] Topics C, F [9] Because the FDA requires an ANDA to be tied to a particular supplier's API, Topics C, F [10]

Topic I

[3] Topics C, F " Dkt. No. 182-38.
[4] Dkt. No. 187-34 at p. 12.
[5] *See* Dkt No. 181-7 ¶ 44, n.43.
[6] Dkt Nos. 181-56; 181-58 at -67; 182-22 at 65:11-67:24; 182-23 at -247_002.
[7] Dkt. Nos. 182-40 at -295–300; 182-41 at -52–71.
[8] Dkt. Nos. 201-3 at 126:25-130:12.
[9] Dkt. Nos. 182-28 at -5360; 182-32 at -94; 182-40 at -295–300.
[10] Dkt. Nos. 181-9 at pp. 10-11; 184-46 at pp. 4-19.

[redacted] [11] [redacted]

[redacted] [12] [redacted]

[redacted] [13] [redacted] [14]

Par's scheme worked. [redacted], Par has successfully delayed generic entry and extended its monopoly through today.[15] [redacted] [16] [redacted] [17]

This Court should deny summary judgment and set the case for trial because:

- ***First***, there are disputes of fact regarding antitrust injury. [redacted]

[11] Dkt. No. 181-42 at 207:2-25.
[12] Dkt. No. 182-26.
[13] Dkt. No. 181-1 at pp. 20, 22, 63-66. [redacted] *Id.* at pp. 63-64.
[14] *See* Dkt. No. 181-1 at pp. 18-22, 47-49.
[15] *See* Dkt. No. 181-56.
[16] Dkt. No. 181-1 at pp. 29-31, 34-35.
[17] Dkt. Nos. 181-51; 181-53.

Topics C, F

Topic H

- ***Second***, there are disputes of fact regarding anticompetitive effects and substantial foreclosure. Par argues there were other API suppliers available to Fresenius Kabi beyond BCN, Bachem, and PolyPeptide, but those alleged suppliers were not viable during the relevant time. The same evidence led the Second Circuit to reverse summary judgment in *Geneva Pharm. Tech. Corp. v. Barr Labs. Inc.*, 386 F.3d 485, 502-09 (2d Cir. 2004). Accordingly, the "suppliers" Par identifies could not have prevented delay of competition.

- ***Third***, there are disputes of fact regarding causation. Fresenius Kabi has presented evidence "from which a reasonable jury could conclude" that Fresenius Kabi "would have been more likely than not to prevail" in proving Par's Patents invalid in patent litigation, as required to survive summary judgment. *In re Wellbutrin XL Antitrust Litig.*, 868 F.3d 132 (3d Cir. 2017). Further, testimony and data show the formulation of Topics A, F, H Topics A, F, H, which also creates an issue of fact on non-infringement.

After drawing all inferences in Fresenius Kabi's favor, as the Court must, there are disputes of fact precluding summary judgment.

PROCEDURAL BACKGROUND

The Third Circuit reversed this Court's grant of summary judgment for Par. The Third Circuit did *not* invite this Court to rule for Par on remand. Rather, the Third Circuit held, "*Wellbutrin* required the District Court to examine the record to determine whether a reasonable jury could find that Par's patents would have blocked Fresenius Kabi's market entry," and remanded the case for that analysis. CA3 Op. 10. The Third Circuit also stated, "[o]n remand, the District Court may choose to consider whether" Par's conduct was anticompetitive. *Id.* at 10 n.12. The

Third Circuit identified many facts that bear on this analysis and stated that, "[i]f the District Court chooses to consider whether Par engaged in anticompetitive conduct, it is for that Court to decide whether there are disputes of material fact concerning these points and others that may be relevant." *Id.* Because there *are* disputes of material fact, this Court should deny summary judgment.

ARGUMENT

I. There are disputes of fact regarding antitrust injury.

Conduct that *delays* generic competition causes antitrust injury.[18] *Wellbutrin*, 868 F.3d at 151-52; *Glumetza*, 2021 WL 1817092, at *12 (delayed generic entry "certainly counts as a valid antitrust injury"). By delaying Fresenius Kabi's ANDA filing, Par delayed generic competition as a whole, causing consumers to pay significantly higher prices. **Topics A, F** . Dkt. Nos. 184-38; 181-66. Because of Par, Fresenius Kabi could not file that ANDA, **Topic O** Dkt. No. 181-1 at p. 26. To date, no generic has entered the market, and Par has continued raising prices.

Par argues there was no antitrust injury because Fresenius Kabi had the **Topics C, F** , **Topic H**

[18] Antitrust injury is an "injury of the type the antitrust laws were intended to prevent." *Brunswick Corp. v. Pueblo Bowl-O Mat, Inc.*, 429 U.S. 477, 488 (1977).

Topic H

.[19] This alone establishes Fresenius Kabi had no actual opportunity to compete. Moreover, the Third Circuit does not require futile efforts at competition. *See United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 193, 196 (3d Cir. 2005) ("possible" competition that is not "practicable" or "feasible" could not justify district court decision finding no antitrust violation and stating, "[t]he District Court erred when it … focused on a theoretical feasibility of success"); *see also ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 285 (3rd Cir. 2021) (outbidding not "realistic" when monopolist interferes with the competitive process).

At the very least, whether Fresenius Kabi had an opportunity to compete is an issue of fact. Fresenius Kabi could only have the opportunity to compete for a **Topics C, F** if Par did not exercise "undue interference or coercion." *See Race Tires Am., Inc. v. Hoosier Racing Tire Corp.*, 614 F.3d 57, 83-84 (3d Cir. 2010).

Topics C, F

[20]

[19] Dkt. No. 201-3 at 126:25-130:12. **Topics B, C, F**

Dkt. No. 181-1 at p. 34.

[20] Dkt. No. 182-23 at -247 002. **Topics C, F**

Dkt. Nos. 182-2; 181-72 at 196:7-203:21. Although Par argues Fresenius Kabi should have obtained a written

Topics C, F

Dkt. Nos. 182-26; 182-32. Topics C, F

Topics C, F

. *See* Dkt. Nos. 182-28 at -5360; 182-32. Topics C, F

. Dkt. No. 182-32. Topics C, F This evidence creates an issue of fact. *See ZF Meritor*, 696 F.3d at 284-85 n.17 (when "two reasonable conclusions could be drawn from the evidence" regarding coercion, it is for the jury to decide).[21]

Although Fresenius Kabi was not required to engage in futile competition, Fresenius Kabi consistently Topics C, F. What occurred during those negotiations confirmed Par was calling the shots. Indeed, after initial discussions, Topics C, F

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supply agreement, Topics C, F. Dkt. No. 181-73 ¶ 18. Nor is there any evidence a contract would have stopped Par's conduct.

[21] In contrast, this was not an issue of fact in *Race Tires* because the evidence showed that the sanctioning bodies preferred the single-tire rule and it was "undisputed" that the race sanctioning bodies had freedom to "ultimately decide[]" whether they wanted exclusivity "in their own best interest." 614 F.3d at 78-79.

[redacted] Dkt. No. 182-36 at -81. [redacted]. Dkt. No. 182-2 at -57.

Par's reliance on *Race Tires* is misplaced because here there was no competitive bidding situation. [redacted]. *See* Dkt. Nos. 182-2; 181-72 at 196:7-203:21. This is not comparable to the competitive process in *Race Tires*. 614 F.3d at 83.

Furthermore, *LePage's* establishes that significant monetary payments, [redacted], can be coercive. 324 F.3d at 154, 160-61 (crediting district court's analysis that "the jury could have reasonably concluded that [the defendant's] customers were *forced* to forego purchasing" from a competitor to obtain rebates ranging from $200,000 to $1.5 million) (emphasis added). [redacted]

[redacted].[22] [redacted]

[redacted]

[redacted]

[redacted][23] Accordingly, unlike *Race Tires*, [redacted]—which is anticompetitive. *See In re Lorazepam & Clorazepate Antitrust Litig.*, 467 F. Supp. 2d 74, 78 (D.D.C. 2006) (affirming jury verdict where the defendant shared monopoly profits with API supplier to obtain exclusivity).

In addition to [redacted], Par's argument that [redacted] is baseless.[24] Had Fresenius Kabi secured [redacted]

[redacted]

[redacted]. Dkt. Nos. 181-80 at 146:2-22. Par cites no case for the absurd proposition that an antitrust plaintiff must try to take a product off the

[22] *See* Dkt. Nos. 182-28 at -5360; 182-32.
[23] Dkt. Nos. 182-40 at -295-300; 182-41 at -52-71.
[24] Although Par argues that exclusive contracts "generally pose little threat to competition," there are plenty of circumstances where exclusive contracts *do* harm competition. *See, e.g.*, *LePage's*, 324 F.3d at 159-63; *Dentsply Int'l, Inc.*, 399 F.3d at 191-96; *ZF Meritor*, 696 F.3d at 286-88; *Geneva*, 386 F.3d at 502-06; *In re Lorazepam*, 467 F. Supp. 2d at 82-87.

market, thus harming consumers, to establish antitrust injury.[25] Regardless, Fresenius Kabi had no opportunity to compete Topics C, F due to Par's conduct.

All of this evidence creates an issue of fact and precludes summary judgment.

II. There are disputes of fact regarding anticompetitive effects.

Exclusive contracts are anticompetitive if they "substantially lessen competition." CA Op. 10 n.12. One consideration is whether there is "substantial foreclosure of the market for the relevant product." *Id.*[26] The test is *not* total foreclosure, but whether the conduct prevents "one or more" competitors from "gaining a foothold in the market." *LePage's*, 324 F.3d at 158–59.

Topic I

Dkt. No. 172-4 at p. 6. Topic I

.[27]

Topics C, F

. This creates an issue of fact on substantial foreclosure.[28]

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[25] Par's reliance on *Nat'l Soc. of Pro. Engineers v. United States*, 435 U.S. 679, 696 (1978), is misplaced because, there, competitive bidding did not remove a product from the market and it benefitted consumers by lowering prices.

[26] Other considerations include whether the defendant is a monopolist, and "likely or actual anticompetitive effects … including whether there was reduced output, increased price, or reduced quality in goods or services." *Id.*

[27] Dkt. No. 181-42 at 60:2–17.

[28] *See LePage's*, 324 F.3d at 158–59 (substantial foreclosure established without percentage because "the jury could have reasonably found that [defendant's] exclusionary conduct cut [plaintiff] off from key retail pipelines"); *Dentsply Int'l, Inc.*, 399 F.3d at 189–90, 197 (foreclosure shown without percentage where

Par does not cite a single Third Circuit case requiring Fresenius Kabi to "define a market for API supply" to establish substantial foreclosure. If Par were correct, virtually all exclusive dealing cases would have two defined markets, but the Third Circuit has only required one.[29] Indeed, in similar cases, the relevant market is the drug, not its API. *See In re Lorazepam*, 467 F. Supp. 2d at 86; *see also Fera Pharms., LLC v. Akorn, Inc.*, 2015 WL 10793136 (S.D.N.Y. Sept. 3, 2015).[30] In such cases, courts have found that exclusive contracts substantially foreclose competition *without* calculating a foreclosure percentage of the API markets. *See Geneva*, 386 F.3d at 502-04; *Lorazepam*, 467 F. Supp. 2d at 83-84. Regardless, Topic I

Topic I

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Par's true argument is not about market definition or foreclosure percentage anyway; it is about whether there were viable suppliers of vasopressin API beyond BCN, Bachem, and PolyPeptide—**Topics C, F**. Similar antitrust cases involving exclusive API deals establish the viability of alternative API suppliers is an issue of fact that should not be resolved on summary

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evidence showed defendant "effectively choked off the market" by locking up key dealers); *McWane, Inc. v. F.T.C.*, 783 F.3d 814, 837–38 (11th Cir. 2015) (FTC "did not place an exact number on the percentage foreclosed," but established substantial foreclosure with evidence the defendant "tied up the key dealers").

[29] *See ZF Meritor*, 696 F.3d at 264 (defining one market: truck transmissions); *Dentsply*, 399 F.3d at 184 (defining one market: artificial teeth); *LePage's*, 324 F.3d at 161 (defining one market: transparent tape).

[30] The plaintiff defined two markets (the drug and API) in *Geneva* only because the plaintiff alleged separate monopolization claims for *each* market. 386 F.3d at 501.

judgment. *Geneva*, 386 F.3d at 508-09 (reversing summary judgment); *Lorazepam*, 467 F. Supp. 2d at 78, 83-84, 87 (upholding jury verdict).

Fresenius Kabi's evidence is nearly identical to the evidence that allowed the plaintiff to survive summary judgment in *Geneva*. 386 F.3d at 502-04, 508-09. Although Par cited thirteen supposedly alternative API "suppliers," the evidence shows that none were viable during the relevant time Topics A, C, F :

- Topics A, C, F . Nos. 174-7;181-71; 182-69 at 265:13-267:7; 183-55 at -97.
- Topics A, C, F . *See* Dkt. Nos. 174-7; 181-71; 183-56; 183-57; 183-58; 182-69 at 267:8-275:8; 183-59.
- There is no evidence any oxytocin suppliers ever started development and none have filed DMFs. Dkt. No. 174-7; *see also* Dkt. No. 183-39 ¶ 66.
- Topics A, C, F Dkt. Nos. 174-7; 179 ¶¶ 487-99.
- Topics A, C, F Dkt. Nos. 174-7; 171-13.

[31] Although the Third Circuit held that the absence of a DMF is not dispositive, it did *not* hold that the absence of a DMF is *irrelevant*. CA3 Op. 10 n.12; *see also Geneva*, 386 F.3d at 502 (absence of DMF a relevant consideration for determining whether an API supplier is viable). Accordingly, a jury can consider this evidence. Notably, none of the API suppliers Par contends were viable had DMFs Topics A, C, F Topics A, C, F and the majority still do not have DMFs today.

- Topics A, C, F [32] Dkt. Nos. 174-7; 179 ¶¶ 487-500.
- Topics A, C, F . Dkt. No. 179 ¶¶ 496-500. Topics A, C, F *Id.* ¶¶ 499-505.

This evidence creates an issue of fact on whether these potential suppliers were viable at the relevant time. Indeed, Topic I [33] confirming that anticompetitive effects and foreclosure can be assessed without either one.

Although certain generic manufacturers, Topics A, C, F may someday enter the market, that has no bearing on whether Par's conduct substantially foreclosed and delayed competition. In both *Geneva* and *Lorazepam*, competitors were *eventually* able to access API despite the defendants' exclusive contracts, yet substantial foreclosure was still an issue of fact. *See Geneva*, 386 F.3d at 494, 502-04; *Lorazepam*, 467 F. Supp. 2d at 84.

Finally, Par's conduct harmed competition as a whole (and not just Fresenius Kabi) because Par's conduct delayed generic competition, causing consumers to pay

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[32] Topics A, C, F Dkt. No. 174-7.

[33] *See* Dkt. Nos. 181-1; 181-8; 183-54.

higher prices. *See FTC v. AbbVie Inc.*, 976 F.3d 327, 351-56 (3d Cir. 2020) (delayed generic entry causes anticompetitive effects). Fresenius Kabi was not required also to establish Par harmed other competitors. *LePage's*, 324 F.3d at 159 (foreclosure of "one significant competitor" enough). Regardless, other drug manufacturers were harmed by Par's conduct. **Topics C, F, L, M. N** . *See* Dkt. Nos. 181-1 at pp. 19-21, 47-49. **Topics E, L, M** .[34] All of this evidence creates an issue of fact on whether Par's conduct was anticompetitive and substantially foreclosed competition.

III. Fresenius Kabi's Causation Evidence Satisfies *Wellbutrin*.

The Third Circuit held that the parties' causation arguments "trigger[] a patent analysis under *Wellbutrin*." CA3 Op. 9. Under *Wellbutrin*, Fresenius Kabi survives summary judgment if it has "produce[d] evidence from which a reasonable jury could conclude" that Fresenius Kabi "would have been more likely than not to prevail" in patent litigation filed by Par. *See Wellbutrin*, 868 F.3d at 167-69.

Fresenius Kabi has two independent causation theories—invalidity and non-

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[34] **Topics C, E, F, M** *See* Dkt. Nos. 181-1 at pp. 47–49. **Topics C, E, F, M** . *Id.* at p. 26; Dkt. No. 151-88. **Topics C, E, F, L** Dkt. Nos. 151-70; 183-70 at p. 14.

infringement—and survives summary judgment by satisfying *Wellbutrin* with respect to either one. To satisfy *Wellbutrin*, Fresenius Kabi presented the same expert and documentary evidence it would have presented in actual patent litigation. Just as the prevailing party in *Wellbutrin* did, Fresenius Kabi also presented testimony from a patent law expert that Topic K . This evidence satisfies *Wellbutrin*'s standard to get to a jury.

A. Fresenius Kabi's invalidity evidence satisfies *Wellbutrin*.

Whether Par's Patents are invalid for obviousness is a fact-intensive inquiry subject to expert testimony.[35] In two reports totaling nearly 400 pages, Dr. Ralph Tarantino, Fresenius Kabi's drug formulation expert, undertook this detailed, factual analysis and opined that each asserted claim of Par's Patents is invalid for obviousness.[36] Topic K . Dkt. Nos. 187-29; 183-45 at

[35] Patents are invalid for obviousness "when 'the differences between the subject matter sought to be patented and the prior art are such that the subject matter … would have been obvious … to a person having ordinary skill in the art.'" *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007) ("*KSR*") (quoting 35 U.S.C. § 103). Assessing obviousness requires several factual inquiries: (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the art; and (4) secondary considerations of nonobviousness. *Id.* at 406.

[36] The asserted claims are: (1) claim 1 of the '478 patent (Dkt. No. 187-19); (2) claims 1-4, 12 and 14-19 of the '526 patent (Dkt. No. 187-20); (3) claims 1-8, 12 and 13 of the '209 patent (Dkt. No. 187-21); (4) claims 1 and 3-11 of the '785 patent (Dkt. No. 187-22); (5) claims 1-4 and 15-19 of the '239 patent (Dkt. No. 187-23).

179:2-21. Topic K

.[37] Topic K

[38] Topic K

.[39]

Topic K

.[40]

See, e.g., Dkt. No. 183-41 at 129 Topic K

Topic K

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[37] *Compare* Dkt. No. 187-29 at -39-40 *with* Dkt. Nos. 187-19 at -821; *see also* Dkt. Nos. 187-20; 187-21; 187-22; 187-23; 183-41.

[38] Dkt. Nos. 187-29 at -39-40, -44; 187-20; 187-21; 187-22; 187-23

[39] Fresenius Kabi's invalidity evidence also included the expert opinions of Dr. Aaron Waxman, a medical doctor with approximately twenty years of firsthand experience administering vasopressin to treat patients. Dkt. No. 181-6 at pp. 3, 14. Beyond obviousness, Topic K Dkt. No. 183-41 at pp. 306-19. Par has not challenged any of this evidence.

[40] Par's argument to the contrary was previously raised by Par in a *Daubert* motion filed at the start of summary judgment briefing, *see* Dkt. No. 162, but Par allowed its *Daubert* motions to be terminated until after summary judgment. Dkt. No. 178. Thus, Par has waived pre-summary judgment *Daubert* motions and this argument, erroneous as it is, should not even be considered.

Topic K .[41] Topic K

.[42] Accordingly, Dr. Tarantino's analysis was proper.

B. Fresenius Kabi's non-infringement evidence satisfies *Wellbutrin*.

There is more than enough evidence to analyze Fresenius Kabi's non-infringement causation theory under *Wellbutrin*. Par's argument to the contrary is nearly identical to the argument the Third Circuit just rejected, and this Court should not entertain it.[43] Regardless, the record establishes the formulation of Fresenius Kabi's Topics A, F. To file an ANDA, a company must manufacture the proposed product and collect six months of stability data. Dkt. No. 163 ¶¶ 68-69. Topics A, C, F

. Dkt. Nos. 184-24; 184-25; 184-26; 184-27; 184-38. That data is part of the record and establishes the product's formulation. *Id*. Topics A, F

[41] Dkt. Nos. 183-41 at p. 132; 184-4 at p. 26. Topic K

" Dkt. Nos. 196-31 at 181:8-13 (emphasis added); 183-44 at pp. 57-58.

[42] *See KSR*, 550 U.S. at 419-20 ("[A]ny need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed."); *Norgren Inc. v. Int'l Trade Comm'n*, 699 F.3d 1317, 1323 (Fed. Cir. 2012) (the relevant problem in the art "includes, but is not limited to, the problem motivating the patentee.").

[43] The Third Circuit held *Wellbutrin* does "not require…an ANDA be filed for a court to determine whether the patent breaks the chain of causation." CA3 Op. 9.

Topics A, F

.[44] Thus, it is disingenuous for Par to say there is "no evidence" of Fresenius Kabi's formulation.

In contrast, there are no documents or data *whatsoever* supporting Par's argument that, Topics A, F

. At best, Par's argument creates an issue of fact,[45] but it does not "absolve[]" the Court from applying *Wellbutrin* to non-infringement.

To satisfy *Wellbutrin*, Fresenius Kabi again presented the testimony of its drug formulation expert, Dr. Tarantino, Topic K

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[44] Topics A, F

Dkt. Nos. 181-66 at -40; 184-24; 184-25; 184-26; 184-27. Topics A, F

. Dkt. No. 184-38 at p. 6. Being the first filer is important even when there is no patent because the first generic captures the highest share. *See* Dkt. No. 183-39 at p. 4.

[45] *See Glumetza*, 2021 WL 1817092, at *15 (whether but-for world conduct would have differed from the actual world "remains a question for our jury").

Topic K.[46] Par does not contest this evidence or Dr. Tarantino's conclusions of non-infringement.

Par also cannot prove infringement of the remaining '239 patent for two independent reasons. First, Par has granted Fresenius Kabi a retroactive covenant not to sue on the '239 patent, extinguishing any infringement claim.[47] Second, Par has failed to put forward any evidence that all elements of the '239 patent claims are present Topics A, F, which is Par's burden. *See Glumetza*, 2021 WL 1817092, at *9 (rejecting argument that plaintiff must prove non-infringement to establish causation in antitrust case because "[t]he patent owner *always* bears [the] burden" of establishing infringement) (emphasis in original). Even if Par could overcome these deficiencies, infringement of the '239 patent is the subject of competing expert opinions, thereby foreclosing summary judgment.[48]

C. Fresenius Kabi's "likely outcome" evidence satisfies *Wellbutrin*.

On top of the evidence from its technical experts, which is itself sufficient under *Wellbutrin*, Fresenius Kabi also presented the testimony of Professor John

[46] Dkt. Nos. 183-41 at pp. 324, 327–29, 332; 184-4 at pp. 52–57.
[47] Order, *Par Pharmaceutical, Inc. et al. v. Amneal Pharmaceuticals of New York, LLC*, 18-cv-2032, Dkt. 204 (D. Del. Aug. 7, 2020). That the causation inquiry focuses on the but-for world does not absolve Par of its real-world contractual obligations. Thus, Par cannot argue the '239 patent to a jury.
[48] *See* Dkt. Nos. 172-19 at 144:4-25 (opining Fresenius Kabi's product would not have met all limitations of claim 1 of the '239 patent); 183-41 at p. 325 (other asserted '239 patent claims are not infringed); 183-41 at p. 324 (non-infringement opinions on the '239 patent cover both direct and indirect infringement).

Thomas, a patent law expert, that Fresenius Kabi was **Topic K** [redacted].

Dkt. Nos. 183-43 at pp. 25-40; 183-82 at pp. 4-7. Par's argument that this evidence is speculative is once again nearly identical to the argument the Third Circuit just rejected, and should not be revisited.[49] Regardless, the Thomas testimony is not speculative. Not only was such testimony central in *Wellbutrin*, 868 F.3d at 169-70, but courts across the country have admitted such testimony into evidence and denied summary judgment—including in multiple cases involving Professor Thomas.[50] That Par also presented an expert who opined on the probable outcome of patent litigation forecloses Par's argument that such evidence is speculative.[51]

CONCLUSION

For these reasons, the Court should deny Par's motion for summary judgment.

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[49] According to the Third Circuit, a holding that "experts who testify as to the likely outcome of underlying patent litigation … are coming up with probabilities out of whole cloth" would be "irreconcilable" with *Wellbutrin*. CA3 Op. 10 n.11. Moreover, Par waived pre-summary judgment *Daubert* motions. *See* note 40, *supra*.

[50] *In re Intuniv Antitrust Litig.*, No. 1:16-CV-12396, 2020 WL 5995984, at *1 (D. Mass. Oct. 9, 2020) (allowing Thomas testimony and denying summary judgment); *In re Solodyn Antitrust Litig.*, No. 14-md-02503, 2018 WL 563144, at *13-16 (D. Mass. Jan. 25, 2018) (same); *see also In re Loestrin 24 Fe Antitrust Litig.*, 433 F. Supp. 3d 274, 306 (D.R.I. 2019) (allowing similar expert testimony and denying summary judgment); *In re Namenda Direct Purchaser Antitrust Litig.*, 331 F. Supp. 3d 188, 201 (S.D.N.Y. 2018) (same); *United Food & Commercial Workers Local 1776 & Participating Emp'rs Health & Welfare Fund v. Teikoku Pharma USA*, 296 F. Supp. 3d 1142, 1156–61 (N.D. Cal. 2017) (same).

[51] Dkt. No. 183-43 at pp. 40-44, 55.

Dated: May 10, 2021
New York, New York

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 10th day of May, 2021, I caused a true and correct copy of Plaintiff Fresenius Kabi USA, LLC's Supplemental Brief on Summary Judgment Disposition to be (1) provisionally filed under seal electronically with the Clerk of the Court via the Court's CM/ECF system pursuant to L. Civ. R. 5.3(c)(4); and (2) duly served upon all counsel of record in this action via electronic mail as follows:

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